IFW

09/760,807
PATENT
Docket No.: 12013/58101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S)	:	Maria PALASIS
SERIAL NO.	:	09/760,807
FILING DATE	:	January 17, 2001
FOR	:	THERAPEUTIC DELIVERY BALLOON
EXAMINER	:	Loan H. THANH
GROUP ART UNIT	:	3763
CUSTOMER NO.	:	23838

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION PURSUANT TO
37 C.F.R. § 1.182 FOR WITHDRAWAL OF AN
ERRANT ELECTION OF SPECIES

S I R:

The undersigned submits this petition pursuant to 37 C.F.R. § 1.182 seeking reentry of claims withdrawn from the case by the February 24, 2004, and the June 15, 2004, Office actions.

These Office actions have improperly withdrawn more than half of the pending claims without a proper basis under either 37 C.F.R. § 1.142 or 37 C.F.R. § 1.146. All but two of the withdrawn claims have been pending in the case for three years. Moreover, all of the subject matter of the withdrawn claims has been examined on multiple occasions. Simply put, it is too late in the game to slice up the case and exclude claims from further examination.

Background

The February 24, 2004, Office action and the June 15, 2004, Office action have combined to improperly withdraw claims 4, 6-7, 11, 13, 15, 17-19, 22, and 25-27, from the case. As neither Office action provides a proper basis, the withdrawn claims should be reinstated.

The February 24, 2004, Office action, which is self-entitled "Election/Restriction," provides no clear basis for the restriction of independent and distinct inventions under 37 C.F.R. § 1.142 or for the election of species under 37 C.F.R. § 1.146. Instead, the Office action improperly blends the requirements and provisions of each of these sections to justify its contentions. The Office action first suggests that an election of species is sought "due to the burden applicant is placing on the Examiner with the different patentably distinct species claimed." However, the Office action then suggests that it actually seeks restriction, rather than election of species, when it notes that "no claims are generic."

The June 15, 2004, Office action finalizes this errant "Restriction/Election" and provides, for the first time, a list of claims withdrawn from consideration.

Argument

37 C.F.R. § 1.146 – Election of Species - provides that "[i]n the first office action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant ... to elect a species." Thus, an election of species may only be made in the first Office action, and then, only if one or more generic claims are present.

Here, however, the requested election has come deep into the prosecution of the case, years after the first Office action of February 27, 2002, and years after the subject matter of the claims was first examined. Because the election is untimely and follows several Office actions

on the merits,[1] there is no basis whatsoever to withdraw any of the claims as containing a non-elected species.

37 C.F.R. § 1.142 – Requirement for Restriction – provides that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require the applicant in the reply ... to elect an invention." If, however, the "search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits." See MPEP 803 (emphasis added).

In this case, restriction of the claims can not be proper because the subject matter of each of the pending claims has already been searched. Thus, there can be no credible argument that a serious burden on the examiner now exists, justifying restriction. See generally Exhibit A (showing the additions to the claims that the Office action argues triggers the disputed Restriction/Election).

Moreover, the search classification for all of the claims (both pending and withdrawn) has been and remains the same, surgery (class 604). Thus, there is no credible reason to believe that future searches will stray from this field of search, restriction is simply not needed. See MPEP § 808.02 (noting that where "the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among related inventions") (emphasis added).

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[1] Prosecution Chronology - **This application was originally filed on 1/17/01 with twenty-five claims. The first Office action of 2/27/02 examined and rejected all twenty-five of these claims. Some of them were amended by the Applicant and then all of them were re-examined in the next Office action, mailed 7/24/04, which was made final. An RCE and preliminary amendment, which amended several claims and withdrew claims 5, 16, and 24, were filed on 11/25/02. An Office action was mailed on February 28, 2003. This Office action examined the pending twenty-two claims, rejecting each one. The next Office action, mailed September 10, 2003, responded to the intervening response, and again examined and rejected or objected to the pending twenty-two claims. An amendment was filed on December 2, 2003, and the February 24, 2004, Restriction was mailed in response.**

Conclusion

For at least these reasons, the undersigned hereby petitions that the withdrawn claims, numbered 4, 6-7, 11, 13, 15, 17-19, 22, and 25-27, be reinstated in the case and continue to be examined on the merits.

Should any fees be due in conjunction with this petition, the Commissioner is hereby authorized to charge Kenyon & Kenyon's deposit account no. 11-0600.

Respectfully submitted,

Date: August 31, 2004

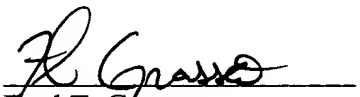

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EXHIBIT A

1. (Currently Amended) A system for delivering therapeutic to an irregular interior vessel surface comprising:

a catheter having a proximal end, a distal end, and an internal lumen;

a source of fluid in communication with the internal lumen of the catheter; and

a first inflatable balloon having an exterior surface,

the first inflatable balloon in communication with the internal lumen of the catheter,

the first inflatable balloon having a measurable elasticity,

the exterior surface of the first inflatable balloon at least partially covered with a therapeutic when the first inflatable balloon is in an initial unexpanded state;

the exterior surface of the first inflatable balloon in communication with a therapeutic when the first inflatable balloon is in an expanded state; and

a dilation bladder located within the first inflatable balloon,

the dilation bladder in fluid communication with a second internal lumen of the catheter by way of a dilation bladder openings in the catheter,

the dilation bladder deformable from a non-inflated position to an inflated position.

the dilation bladder having a measurable elasticity, the elasticity of the first inflatable balloon being greater than the elasticity of the dilation bladder,

~~wherein the first inflatable balloon may be inflated without inflating the dilation bladder~~.

2. (Currently Amended) The system for delivering therapeutic of claim 1 wherein the exterior surface of the first inflatable balloon is contacting ~~covered with~~ a therapeutic when the first inflatable balloon is in an initial unexpanded state.

3. (Original) The system for delivering therapeutic of claim 1 further comprising:

a source of therapeutic, the source of therapeutic in fluid communication with the exterior surface of the first inflatable balloon.

4. (Original) The system for delivering therapeutic of claim 3 wherein the therapeutic traverses through a section of the first inflatable balloon before the therapeutic comes in communication with the exterior surface of the first inflatable balloon.

5. (Canceled)

6. (Currently Amended) The system for delivering therapeutic of claim 1 further comprising:

a second inflatable balloon, the second inflatable balloon located within the first inflatable balloon, the second inflatable balloon having an outside surface, the outside surface in communication with a source of therapeutic, the first inflatable balloon having a plurality of apertures in fluid communication with the outside surface of the second inflatable balloon.

7. (Currently Amended) The system for delivering therapeutic of claim 1 further comprising:

a ~~second~~ third internal lumen within the catheter, the first inflatable balloon positioned around the ~~second~~ third internal lumen, the ~~second~~ third internal lumen having an entrance orifice and an exit orifice, the entrance orifice positioned upstream of the inflatable balloon, upstream relative to a fluid flowing through the irregular interior vessel, and the exit orifice positioned downstream of the inflatable balloon, downstream relative to fluid flowing through the irregular interior vessel.

8. (Original) The system for delivering therapeutic of claim 1 wherein the first inflatable balloon is made with a latex material and wherein the source of fluid is adapted to control the rate of inflation of the balloon.

9. (Original) The system for delivering therapeutic of claim 1 wherein the first inflatable balloon is made with a silicone material and wherein the source of fluid is adapted to control the rate of inflation of the balloon.

10. (Original) The system for delivering therapeutic of claim 1 wherein the first inflatable balloon is made with a polyurethane material and wherein the source of fluid is adapted to control the rate of inflation of the balloon.

11. (Original) The system for delivering therapeutic of claim 1 wherein the first inflatable balloon is porous relative to the therapeutic being delivered.

12. (Currently Amended) A device for delivering therapeutic to an irregular interior vessel surface comprising:

a catheter having a proximal end, a distal end, and an internal lumen;

a first inflatable balloon in fluid communication with the internal lumen of the catheter, the first inflatable balloon having a measurable elasticity, the first inflatable balloon having an exterior surface and an interior surface, the exterior surface of the first inflatable balloon at least partially covered with a therapeutic, the first inflatable balloon being impervious to the therapeutic;

a dilation bladder located within the first inflatable balloon,

the dilation bladder in fluid communication with a second internal lumen of the catheter by way of a dilation bladder openings in the catheter,

the dilation bladder deformable from a non-inflated position to an inflated position.

13. (Previously Presented) The device of claim 12 wherein a surface of the first inflatable balloon contains grooves sized to increase the deformability of the inflatable balloon.

14. (Previously Presented) The device of claim 12 further comprising:

a source of therapeutic, the source of therapeutic in fluid communication with the exterior surface of the first inflatable balloon.

15. (Previously Presented) The device of claim 14 wherein the therapeutic traverses through the first inflatable balloon before the therapeutic contacts the exterior surface of the first inflatable balloon.

16. (Canceled)

17. (Currently Amended) The device of claim 12 further comprising:

a third ~~the second~~ internal lumen passing through the first inflatable balloon, the first inflatable balloon positioned around the third ~~second~~ internal lumen,

the third ~~second~~ internal lumen having an entrance orifice and an exit orifice,

the entrance orifice positioned upstream of the first inflatable balloon, upstream relative to a fluid flowing through the irregular interior vessel, and the exit orifice positioned downstream of the first inflatable balloon, downstream relative to fluid flowing through the irregular interior vessel.

18. (Previously Presented) The device of claim 12 further comprising:

a second balloon positioned between the dilation bladder and the first inflatable balloon, the second balloon having an outside surface, the outside surface in communication with therapeutic.

19. (Currently Amended) The device of claim 12 wherein the first inflatable balloon ~~is made with~~ has an internal grooved ~~material~~ balloon surface.

20. (Currently Amended) A method for delivering therapeutic to an irregular interior vessel surface of a patient comprising:

inserting an expandable first membrane attached to a catheter into the vessel of the patient, the expandable first membrane having an exterior surface in contact with therapeutic and having a measurable elasticity;

positioning the expandable first membrane at the irregular interior vessel surface within the patient;

forcing a fluid into the expandable first membrane after positioning the expandable first membrane at the irregular interior vessel surface to inflate the expandable first membrane, the expandable first membrane becoming juxtaposed to and replicating the irregular interior surface of the vessel of the patient; and,

after positioning the expandable first membrane at the irregular interior surface of the vessel within the patient, inflating a dilation bladder located within the expandable first membrane, the dilation bladder having a measurable elasticity, the elasticity of the first inflatable balloon being greater than the elasticity of the dilation bladder.

21. (Currently Amended) The method of claim 20 wherein the exterior surface of the expandable first membrane is ~~in communication with a~~ impervious to therapeutic.

22. (Currently Amended) The method of claim 20 further comprising:

~~pushing a therapeutic over the exterior surface of the expandable first membrane after the expandable first membrane is positioned at the irregular interior surface of the vessel~~

providing access to a channel within the catheter to enable blood in the vessel of the patient to flow through the catheter.

23. (Currently Amended) The method of claim ~~22~~ 20 wherein ~~the therapeutic is pushed through the expandable first membrane to reach the exterior surface of the expandable first membrane and wherein~~ the fluid is a tracing fluid.

24. (Canceled)

25. (Currently Amended) The method of claim 20 further comprising:

opening an entrance orifice of a passage traversing the expandable first membrane, the passage compatible with the fluid flowing within the vessel of the patient ~~patient's body~~.

26. (New) A medical device for delivery of therapeutic to a vessel within a patient comprising:

a catheter body having a first end, a second end, and a lumen within the catheter body; and

an inflatable balloon in fluid communication with the lumen of the catheter, the balloon comprising a grooved surface of the balloon, the grooved surface comprising ribs or notches.

27. (New) The medical device of claim 26 further comprising a dilation bladder, the dilation bladder positioned inside of the inflatable balloon,

the inflatable balloon and the dilation bladder each having a measurable elasticity, the elasticity of the inflatable balloon being greater than the elasticity of the dilation bladder.

AFTER FINAL
PATENT
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RESPONSE TO JUNE 15, 2004, FINAL OFFICE ACTION AND INTERVIEW SUMMARY

S I R:

This is a response to the final Office Action of June 15, 2004, which set a three-month period of response extending to and including September 15, 2004.

This paper also contains a summary of the August 3, 2004, Examiner's Interview.

The Commissioner is hereby authorized to charge any fees associated with this filing to Kenyon & Kenyon deposit account no. 11-0600.

IN THE CLAIMS:

1. (Previously Presented) A system for delivering therapeutic to an irregular interior vessel surface comprising:

a catheter having a proximal end, a distal end, and an internal lumen;

a source of fluid in communication with the internal lumen of the catheter; and

a first inflatable balloon having an exterior surface,

the first inflatable balloon in communication with the internal lumen of the catheter,

the first inflatable balloon having a measurable elasticity,

the exterior surface of the first inflatable balloon at least partially covered with a therapeutic when the first inflatable balloon is in an initial unexpanded state,

the exterior surface of the first inflatable balloon in communication with a therapeutic when the first inflatable balloon is in an expanded state; and

a dilation bladder located within the first inflatable balloon,

the dilation bladder in fluid communication with a second internal lumen of the catheter by way of a dilation bladder opening in the catheter,

the dilation bladder deformable from a non-inflated position to an inflated position,

the dilation bladder having a measurable elasticity, the elasticity of the first inflatable balloon being greater than the elasticity of the dilation bladder.

2. (Previously Presented) The system for delivering therapeutic of claim 1 wherein the exterior surface of the first inflatable balloon is contacting a therapeutic when the first inflatable balloon is in an initial unexpanded state.

3. (Original) The system for delivering therapeutic of claim 1 further comprising:

a source of therapeutic, the source of therapeutic in fluid communication with the exterior surface of the first inflatable balloon.

4. (Withdrawn) The system for delivering therapeutic of claim 3 wherein the therapeutic traverses through a section of the first inflatable balloon before the therapeutic comes in communication with the exterior surface of the first inflatable balloon.

5. (Canceled)

6. (Withdrawn) The system for delivering therapeutic of claim 1 further comprising:

a second inflatable balloon, the second inflatable balloon located within the first inflatable balloon, the second inflatable balloon having an outside surface, the outside surface in communication with a source of therapeutic, the first inflatable balloon having a plurality of apertures in fluid communication with the outside surface of the second inflatable balloon.

7. (Withdrawn) The system for delivering therapeutic of claim 1 further comprising:

a third internal lumen within the catheter, the first inflatable balloon positioned around the third internal lumen, the third internal lumen having an entrance orifice and an exit orifice, the entrance orifice positioned upstream of the inflatable balloon, upstream relative to a fluid flowing through the irregular interior vessel, and the exit orifice positioned downstream of the inflatable balloon, downstream relative to fluid flowing through the irregular interior vessel.

8. (Original) The system for delivering therapeutic of claim 1 wherein the first inflatable balloon is made with a latex material and wherein the source of fluid is adapted to control the rate of inflation of the balloon.

9. (Original) The system for delivering therapeutic of claim 1 wherein the first inflatable balloon is made with a silicone material and wherein the source of fluid is adapted to control the rate of inflation of the balloon.

10. (Original) The system for delivering therapeutic of claim 1 wherein the first inflatable balloon is made with a polyurethane material and wherein the source of fluid is adapted to control the rate of inflation of the balloon.

11. (Withdrawn) The system for delivering therapeutic of claim 1 wherein the first inflatable balloon is porous relative to the therapeutic being delivered.

12. (Currently Amended) A device for delivering therapeutic to an irregular interior vessel surface comprising:

a catheter having a proximal end, a distal end, and an internal lumen;

a first inflatable balloon in fluid communication with the internal lumen of the catheter, the first inflatable balloon having a measurable elasticity, the first inflatable balloon having an exterior surface and an interior surface, the exterior surface of the first inflatable balloon at least partially covered with a therapeutic, the first inflatable balloon being impervious to the therapeutic; and

a dilation bladder located within the first inflatable balloon,

the dilation bladder in fluid communication with a second internal lumen of the catheter by way of a dilation bladder openings in the catheter,

the dilation bladder deformable from a non-inflated position to an inflated position.

13. (Withdrawn) The device of claim 12 wherein a surface of the first inflatable balloon contains grooves sized to increase the deformability of the inflatable balloon.

14. (Previously Presented) The device of claim 12 further comprising:

a source of therapeutic, the source of therapeutic in fluid communication with the exterior surface of the first inflatable balloon.

15. (Withdrawn) The device of claim 14 wherein the therapeutic traverses through the first inflatable balloon before the therapeutic contacts the exterior surface of the first inflatable balloon.

16. (Canceled)

17. (Withdrawn) The device of claim 12 further comprising:

a third internal lumen passing through the first inflatable balloon, the first inflatable balloon positioned around the third internal lumen,

the third internal lumen having an entrance orifice and an exit orifice,

the entrance orifice positioned upstream of the first inflatable balloon, upstream relative to a fluid flowing through the irregular interior vessel, and the exit orifice positioned downstream of the first inflatable balloon, downstream relative to fluid flowing through the irregular interior vessel.

18. (Withdrawn) The device of claim 12 further comprising:

a second balloon positioned between the dilation bladder and the first inflatable balloon, the second balloon having an outside surface, the outside surface in communication with therapeutic.

19. (Withdrawn) The device of claim 12 wherein the first inflatable balloon has an internal grooved balloon surface.

20. (Previously Presented) A method for delivering therapeutic to an irregular interior vessel surface of a patient comprising:

inserting an expandable first membrane attached to a catheter into the vessel of the patient, the expandable first membrane having an exterior surface in contact with therapeutic and having a measurable elasticity;

positioning the expandable first membrane at the irregular interior vessel surface within the patient;

forcing a fluid into the expandable first membrane after positioning the expandable first membrane at the irregular interior vessel surface to inflate the expandable first membrane, the expandable first membrane becoming juxtaposed to and replicating the irregular interior surface of the vessel of the patient; and,

after positioning the expandable first membrane at the irregular interior surface of the vessel within the patient, inflating a dilation bladder located within the expandable first membrane, the dilation bladder having a measurable elasticity, the elasticity of the first inflatable balloon being greater than the elasticity of the dilation bladder.

21. (Previously Presented)The method of claim 20 wherein the exterior surface of the expandable first membrane is impervious to therapeutic.

22. (Withdrawn)The method of claim 20 further comprising:

providing access to a channel within the catheter to enable blood in the vessel of the patient to flow through the catheter.

23. (Previously Presented) The method of claim 20 wherein the fluid is a tracing fluid.

24. (Canceled)

25. (Withdrawn) The method of claim 20 further comprising:

opening an entrance orifice of a passage traversing the expandable first membrane, the passage compatible with the fluid flowing within the vessel of the patient.

26. (Withdrawn) A medical device for delivery of therapeutic to a vessel within a patient comprising:

a catheter body having a first end, a second end, and a lumen within the catheter body; and

an inflatable balloon in fluid communication with the lumen of the catheter, the balloon comprising a grooved surface of the balloon, the grooved surface comprising ribs or notches.

27. (Withdrawn) The medical device of claim 26 further comprising a dilation bladder, the dilation bladder positioned inside of the inflatable balloon,

the inflatable balloon and the dilation bladder each having a measurable elasticity, the elasticity of the inflatable balloon being greater than the elasticity of the dilation bladder.

In the Drawings:

Please replace figure 16 with amended figure 16, which is attached.

REMARKS

Claims 1-3, 8-10, 12, 14, 20-21, and 23 are currently pending in this application. Claims 4, 6-7, 11, 13, 15, 17-19, 22, 25-27 have been withdrawn from consideration by the Office action. Each of the pending claims stands rejected.

Interview Summary

A telephonic interview was conducted with the Examiner on August 3, 2004. Discussions during this telephonic interview addressed: (1) the resubmission of paperwork relating to the PTO-1149 form; (2) the new matter rejection of Figure 5; and (3) the withdrawal of claims by the Office action.

As to no. 1, the Examiner indicated that the PTO-1449 form was missing from the file and the undersigned agreed to resubmit the missing paperwork.

As to nos. 2 and 3, no conclusion was reached for the new matter rejection of Figure 5 or for the withdrawal of claims. A petition is being filed regarding the withdrawal of claims and the rejection of Figure 5 is addressed below.

Substantive arguments regarding the §102(b) and §103(a) rejections from the June 15, 2004 Office action were not discussed.

Information Disclosure Statement

The Office action requests the undersigned resubmit PTO-1149 form, which was originally submitted on April 4, 2003. The undersigned has appended the PTO-1149 form, the patents listed on the form, and a photocopy of the postcard indicating that the requested paperwork was originally submitted on April 4, 2003. The undersigned has also included a photocopy of the postcard indicating that this paperwork was previously submitted on December 2, 2003. Acknowledgement that this material was received and considered is requested.

37 C.F.R. §1.83(a) Drawing Objection

"[I]nformation contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter." MPEP §2163.06. Moreover, "the drawings and the specification may be amended to

conform to each other and ... the added matter will not be deemed technical 'new matter' within the prohibition of the law." *In re Heinle*, 52 C.C.P.A. 1164, 1173 (1965).

In this case, the drawing correction of November 25, 2002, has been disapproved for the alleged introduction of new matter. However, the modifications to Fig. 5 do not introduce new matter as the updates simply correlate the drawings with the specification. Support for the objected to grooves on the hyper-deformable balloon can be found in paragraph [0025] of the specifications, which states that "the balloon may be internally ribbed or notched or otherwise specifically configured to increase its deformability...." Furthermore, as previously explained in the Response to the September 10, 2003, Office action, ribbed is defined as "to make with ridges or raised markings," and ridge is defined as a "raised narrow strip." Thus, using these definitions and the other disclosures in the specification, the undersigned submits that one skilled in the art would understand that the specification provides clear support for amended Figure 5.

Figure 16 has been amended herein in response to the Office action's assertion that "the second balloon positioned between the dilation bladder and the first balloon and the grooves in the first balloon must be shown...." The undersigned submits that amended Figure 16, enclosed herein, which now shows the grooves in the first balloon, is not new matter at least for the above reason.

Objections to Claims 2-3

Claim 2 and 3 stand objected to as allegedly failing to further limit the invention. The undersigned requests reconsideration because there are patentable distinctions between these claims.

For one, Claim 2 recites that the "exterior surface of the first inflatable balloon is contacting a therapeutic." This is different than claim 1, which recites "the exterior surface of the first inflatable balloon at least partially covered with a therapeutic." Thus, claim 2 requires contact while claim 1 simply recites covering, which may or may not result in contact.

For another, Claim 3 recites "a source of therapeutic, the source of therapeutic in fluid communication with the exterior surface of the first inflatable balloon." There is no such source anywhere in claim 1.

35 U.S.C. § 102(b) Rejection

Claims 1-3, 8-10, 20-21, and 23 were rejected under 35 U.S.C. §102(b) as being anticipated by Crocker et al. (U.S. Pat. No. 5,295,962). The undersigned submits that Crocker does not disclose or suggest an inflatable balloon wherein "the exterior surface of the first inflatable balloon ... [is] covered with a therapeutic when the first inflatable balloon is in an initial unexpanded state," as in claim 1. The Office action presumes that "Crocker's device is capable [of] releasing the drug through the pores in an unexpanded state." However, Crocker states that "[t]he inflated volume of inflation balloon 30 causes the drug to be expelled by way of ports 40 outside of the drug delivery system." Col. 7, lines 43-45. Hence, Crocker requires the therapeutic to be squeezed out of the balloon during or after inflation in order for the therapeutic to reach the exterior of the balloon. Therapeutic is, therefore, not present in an initial unexpanded state as recited in the claim. For at least this reason, Crocker does not anticipate the claims.

Consistent with the above, the undersigned also submits that Crocker does not disclose or suggest "inserting an expandable first membrane attached to a catheter into the vessel of the patient, the expandable first membrane having an exterior surface in contact with therapeutic" as substantially recited in claim 20. For at least this reason, Crocker does not anticipate claims 20-21 and 23.

35 U.S.C. § 103(a) Rejection

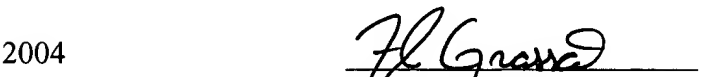
Claims 1-3, 8-10, 12, 14, 20-21 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Brown et al. (US Pat. No. 6,471,672) or Abele et al. (US Pat. No. 5,704,913) in view of Sahatjian (US Pat. No. 5,304,121). The undersigned submits that none of these references disclose or suggest "the elasticity of the first inflatable balloon being greater than the elasticity of the dilation bladder," as substantially recited in claims 1 and 20. As these references do not disclose or suggest this language, there is no need to address the impropriety of combining the references.

CONCLUSION

The Examiner is invited to contact the undersigned to discuss any matter concerning this application.

Respectfully submitted,

Date: August 31, 2004



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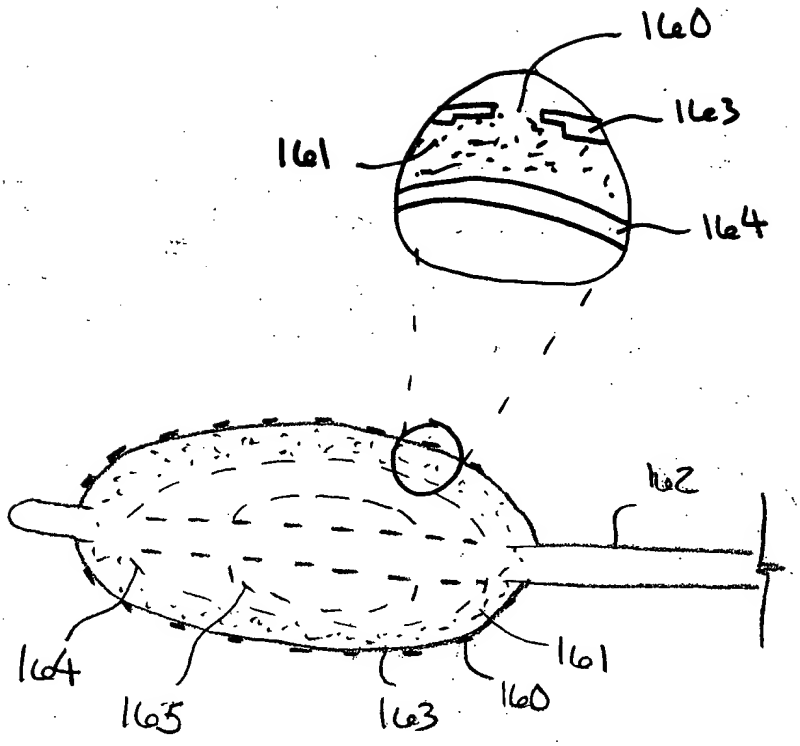

Fig. 16

The stamp of the Patent Office may be taken as acknowledging receipt, on the date stamped, of

INVENTOR(S): **Maria Palasis**
SERIAL NO.: **09/760,807** FILED: **January 17, 2001**
TITLE: **THERAPEUTIC DELIVERY BALLOON**

The PTO is authorized to charge $240.00 fee regarding this filing to Deposit Account No. 11-0600.

PAPERS FILED:

1. INFORMATION DISCLOSURE STATEMENT W/PTO FORM 1449, (2) TWO REFERENCES AND INTERNATIONAL SEARCH REPORT.

Douglas E. Ringel/DLW/vjw **12013/58101** **April 4, 2003**

The stamp of the Patent Office hereon may be taken as acknowledging the receipt, on the date stamped, of

INVENTOR:	**Maria PALASIS**
APPLICATION NO. :	**09/760,807**
FILED:	**January 17, 2001**
TITLE:	***THERAPEUTIC DELIVERY BALLOON***
GROUP ART UNIT:	**3763**

The PTO is authorized to charge or credit any fees regarding this filing to Deposit Account No. 11-0600.

PAPERS FILED:

1. Response to the September 10, 2003 Office Action including;
2. Fig. 16 (one sheet)
3. Information Disclosure Statement dated 4/4/03 with stamped postcard

FTG/paa **12013/58101** **12/2//03**